

## Analysis of Proposed Consent Order to Aid Public Comment

### *In the Matter of Lornamead, Inc., File No. 122 3255*

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing consent order from Lornamead, Inc. (“respondent”). The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

This matter involves respondent’s advertising, marketing, and sale of a line of products including “Lice Shield Shampoo & Conditioner in 1,” “Lice Shield Leave In Spray,” and “Lice Shield Gear Guard” (collectively, “Lice Shield products”). Respondent marketed Lice Shield products in retail stores and on the Internet. According to the FTC’s proposed complaint, respondent promoted Lice Shield products, which contain essential oils such as citronella, as a way to avoid, or to reduce the risk of, getting a head lice infestation (“pediculosis”). Lice Shield products are intended strictly as a means to deter lice, and not as a means to treat an existing head lice infestation. These products do not kill head lice or their eggs.

The proposed complaint alleges that respondent made several claims in various advertisements regarding the efficacy of Lice Shield products to deter lice, including that applying the products to hair or head gear: prevents head lice infestations; decreases the likelihood of an infestation by over 80%; dramatically reduces the likelihood of an infestation during an outbreak; or reduces the likelihood of an infestation during an outbreak. Respondent also allegedly represented that Lice Shield products are more effective when consumers use both the shampoo and the leave-in spray. The proposed complaint alleges that these claims are unsubstantiated and thus violate the FTC Act. Further, the proposed complaint alleges that respondent represented, in various advertisements, that scientific tests prove that, when used as directed, Lice Shield products will significantly reduce the likelihood or chance of a head lice infestation. The complaint alleges that this claim is false and thus violates the FTC Act.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts or practices in the future. Part I of the order prohibits respondent from representing that use of any drug, cosmetic, or pesticide is effective in: a) preventing pediculosis, b) eliminating or reducing the risk of pediculosis by a specific percentage or amount, or c) repelling all lice, or a specific percentage or amount of lice from a person’s head, unless the representation is non-misleading, and, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this Part I, competent and reliable scientific evidence shall consist of at least one adequate and well-controlled human clinical study of the product, or of an essentially

equivalent product, that conforms to an acceptable design and protocol and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true.

Part II of the proposed order prohibits any representation, other than those covered under Part I, that use of any drug, cosmetic, or pesticide, will reduce the risk of a head lice infestation or repel lice, unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, and that are generally accepted in the profession to yield accurate and reliable results.

Part III of the proposed order prohibits any representation, other than those covered under Part I, about the health benefits of any drug, cosmetic, or pesticide, unless the representation is non-misleading, and at the time of making such representation, the respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, and that are generally accepted in the profession to yield accurate and reliable results.

Part IV of the proposed order addresses the allegedly false claim that scientific tests prove that use of Lice Shield products significantly reduces the risk or likelihood of a head lice infestation. Part IV prohibits respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, when advertising any drug, cosmetic, or pesticide.

Part V of the proposed order states that the order does not prohibit respondent from making representations for any drug that are permitted in labeling for that drug under any tentative or final standard promulgated by the Food and Drug Administration (“FDA”), or under any new drug application approved by the FDA.

Part VI of the proposed order requires respondent to pay five hundred thousand dollars (\$500,000) to the Commission. This payment shall be deposited in the United States Treasury as disgorgement.

Parts VII, VIII, IX, and X of the proposed order require respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to its personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations under the

order; and to file compliance reports with the Commission. Part XI provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.